necessary, to the members of the Clinical Laboratory Improvement Advisory Committee.

[57 FR 7185, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993; 60 FR 20051, Apr. 24, 1995; 68 FR 3714, Jan. 24, 2003]

PART 494— CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

Subpart A—General Provisions

Sec.

494.1 Basis and scope.

494.10 Definitions.

494.20 Condition: Compliance with Federal, State, and local laws and regulations.

Subpart B—Patient Safety

494.30 Condition: Infection control.

494.40 Condition: Water and dialysate qual-

494.50 Condition: Reuse of hemodialyzers

and bloodlines. 494.60 Condition: Physical environment.

Subpart C—Patient Care

494.70 Condition: Patients' rights.

494.80 Condition: Patient assessment. 494.90 Condition: Patient plan of care.

494.100 Condition: Care at home.

494.110 Condition: Quality assessment and performance improvement.

494.120 Condition: Special purpose renal dialysis facilities.

494.130 Condition: Laboratory services.

Subpart D—Administration

494.140 Condition: Personnel qualifications. 494.150 Condition: Responsibilities of the medical director.

494.160 [Reserved]

494.170 Condition: Medical records.

494.180 Condition: Governance.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 73 FR 20475, Apr. 15, 2008, unless otherwise noted.

Subpart A—General Provisions

§ 494.1 Basis and scope.

(a) Statutory basis. This part is based on the following provisions:

(1) Section 299I of the Social Security Amendments of 1972 (Pub. L. 92-603), which extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation.

(2) Section 1861(e)(9) of the Act, which requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution.

(3) Section 1861(s)(2)(F) of the Act, which describes "medical and other health services" covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies.

(4) Section 1862(a) of the Act, which specifies exclusions from coverage.

(5) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of erythropoiesis-stimulating agent(s).

(6) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical.

(b) *Scope*. The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

§ 494.10 Definitions.

As used in this part—

Dialysis facility means an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in §413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services.

Discharge means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.